

PATENT COOPERATION TREATY

PCT

INTERNATIONAL PRELIMINARY REPORT ON PATENTABILITY

(Chapter I of the Patent Cooperation Treaty)

(PCT Rule 44*bis*)

Applicant's or agent's file reference 7278WOO1	FOR FURTHER ACTION	See item 4 below
International application No. PCT/US2004/042770	International filing date (<i>day/month/year</i>) 17 December 2004 (17.12.2004)	Priority date (<i>day/month/year</i>) 19 December 2003 (19.12.2003)
International Patent Classification (8th edition unless older edition indicated) See relevant information in Form PCT/ISA/237		
Applicant ABBOTT LABORATORIES		

1.	This international preliminary report on patentability (Chapter I) is issued by the International Bureau on behalf of the International Searching Authority under Rule 44 <i>bis</i> .1(a).																								
2.	This REPORT consists of a total of 6 sheets, including this cover sheet. In the attached sheets, any reference to the written opinion of the International Searching Authority should be read as a reference to the international preliminary report on patentability (Chapter I) instead.																								
3.	<p>This report contains indications relating to the following items:</p> <table style="width: 100%;"> <tr> <td style="width: 10%; text-align: center;"><input checked="" type="checkbox"/></td> <td style="width: 30%;">Box No. I</td> <td style="width: 80%;">Basis of the report</td> </tr> <tr> <td style="text-align: center;"><input type="checkbox"/></td> <td>Box No. II</td> <td>Priority</td> </tr> <tr> <td style="text-align: center;"><input type="checkbox"/></td> <td>Box No. III</td> <td>Non-establishment of opinion with regard to novelty, inventive step and industrial applicability</td> </tr> <tr> <td style="text-align: center;"><input type="checkbox"/></td> <td>Box No. IV</td> <td>Lack of unity of invention</td> </tr> <tr> <td style="text-align: center;"><input checked="" type="checkbox"/></td> <td>Box No. V</td> <td>Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement</td> </tr> <tr> <td style="text-align: center;"><input type="checkbox"/></td> <td>Box No. VI</td> <td>Certain documents cited</td> </tr> <tr> <td style="text-align: center;"><input type="checkbox"/></td> <td>Box No. VII</td> <td>Certain defects in the international application</td> </tr> <tr> <td style="text-align: center;"><input type="checkbox"/></td> <td>Box No. VIII</td> <td>Certain observations on the international application</td> </tr> </table>	<input checked="" type="checkbox"/>	Box No. I	Basis of the report	<input type="checkbox"/>	Box No. II	Priority	<input type="checkbox"/>	Box No. III	Non-establishment of opinion with regard to novelty, inventive step and industrial applicability	<input type="checkbox"/>	Box No. IV	Lack of unity of invention	<input checked="" type="checkbox"/>	Box No. V	Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement	<input type="checkbox"/>	Box No. VI	Certain documents cited	<input type="checkbox"/>	Box No. VII	Certain defects in the international application	<input type="checkbox"/>	Box No. VIII	Certain observations on the international application
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<input type="checkbox"/>	Box No. VIII	Certain observations on the international application																							
4.	The International Bureau will communicate this report to designated Offices in accordance with Rules 44 <i>bis</i> .3(c) and 93 <i>bis</i> .1 but not, except where the applicant makes an express request under Article 23(2), before the expiration of 30 months from the priority date (Rule 44 <i>bis</i> .2).																								

The International Bureau of WIPO 34, chemin des Colombettes 1211 Geneva 20, Switzerland	Date of issuance of this report 20 June 2006 (20.06.2006) Authorized officer <div style="text-align: center; font-weight: bold; font-size: 1.2em;">Ellen Moyse</div>
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PATENT COOPERATION TREATY

AG

From the
INTERNATIONAL SEARCHING AUTHORITY

REC'D 06 MAY 2005

PCT

PCT

To:

14/7

see form PCT/ISA/220

WRITTEN OPINION OF THE INTERNATIONAL SEARCHING AUTHORITY (PCT Rule 43bis.1)

Date of mailing

(day/month/year) see form PCT/ISA/210 (second sheet)

Applicant's or agent's file reference
see form PCT/ISA/220

FOR FURTHER ACTION
See paragraph 2 below

International application No.
PCT/US2004/042770

International filing date (day/month/year)
17.12.2004

Priority date (day/month/year)
19.12.2003

International Patent Classification (IPC) or both national classification and IPC
A23L1/29, A61K31/20

Applicant
ABBOTT LABORATORIES

1. This opinion contains indications relating to the following items:

- ☒ Box No. I Basis of the opinion
- ☐ Box No. II Priority
- ☐ Box No. III Non-establishment of opinion with regard to novelty, inventive step and industrial applicability
- ☐ Box No. IV Lack of unity of invention
- ☒ Box No. V Reasoned statement under Rule 43bis.1(a)(i) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement
- ☐ Box No. VI Certain documents cited
- ☐ Box No. VII Certain defects in the international application
- ☐ Box No. VIII Certain observations on the international application

2. FURTHER ACTION

If a demand for international preliminary examination is made, this opinion will usually be considered to be a written opinion of the International Preliminary Examining Authority ("IPEA"). However, this does not apply where the applicant chooses an Authority other than this one to be the IPEA and the chosen IPEA has notified the International Bureau under Rule 66.1bis(b) that written opinions of this International Searching Authority will not be so considered.

If this opinion is, as provided above, considered to be a written opinion of the IPEA, the applicant is invited to submit to the IPEA a written reply together, where appropriate, with amendments, before the expiration of three months from the date of mailing of Form PCT/ISA/220 or before the expiration of 22 months from the priority date, whichever expires later.

For further options, see Form PCT/ISA/220.

3. For further details, see notes to Form PCT/ISA/220.

Name and mailing address of the ISA:



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**WRITTEN OPINION OF THE
INTERNATIONAL SEARCHING AUTHORITY**

International application No.
PCT/US2004/042770

Box No. I Basis of the opinion

1. With regard to the **language**, this opinion has been established on the basis of the international application in the language in which it was filed, unless otherwise indicated under this item.
 - ☐ This opinion has been established on the basis of a translation from the original language into the following language , which is the language of a translation furnished for the purposes of international search (under Rules 12.3 and 23.1(b)).
2. With regard to any **nucleotide and/or amino acid sequence** disclosed in the international application and necessary to the claimed invention, this opinion has been established on the basis of:
 - a. type of material:
 - ☐ a sequence listing
 - ☐ table(s) related to the sequence listing
 - b. format of material:
 - ☐ in written format
 - ☐ in computer readable form
 - c. time of filing/furnishing:
 - ☐ contained in the international application as filed.
 - ☐ filed together with the international application in computer readable form.
 - ☐ furnished subsequently to this Authority for the purposes of search.
3. ☐ . In addition, in the case that more than one version or copy of a sequence listing and/or table relating thereto has been filed or furnished, the required statements that the information in the subsequent or additional copies is identical to that in the application as filed or does not go beyond the application as filed, as appropriate, were furnished.
4. Additional comments:

**WRITTEN OPINION OF THE
INTERNATIONAL SEARCHING AUTHORITY**

International application No.
PCT/US2004/042770

Box No. V Reasoned statement under Rule 43*bis*.1(a)(i) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

1. Statement

Novelty (N)	Yes: Claims	
	No: Claims	1-14
Inventive step (IS)	Yes: Claims	
	No: Claims	1-14
Industrial applicability (IA)	Yes: Claims	1-14
	No: Claims	

2. Citations and explanations

see separate sheet

Re Item V

**Reasoned statement with regard to novelty, inventive step or industrial applicability;
citations and explanations supporting such statement**

Reference is made to the following documents:

D1: WO-A-9844917

D2: EP-A-0231904

D3: MONATSSCHRIFT FUER KINDERHEILKUNDE, SPRINGER VERLAG, Nr.
143, S.99-104. 1995

NOVELTY (ARTICLE 33(2) PCT)

Remarks:

- For method claims the intended non-medical use is not necessarily limiting the scope of the claim. The effect of a method is an implicit feature of the method itself that will occur automatically.
- The selection of a certain dosage (as in claims 2-4) cannot be used to restore the novelty of a known effect, since the used amount is just a matter of preference of the consumer.

1. Document D1 discloses a method for enhancing the growth of infants by administration of an infant formula containing a combination of docosahexaenoic acid (DHA) and arachidonic acid (ARA)(p.4 §2; p.9 example). The formula contains (per 100 kcal) 3-7g lipids, 1-5g proteins and 8-12 g carbohydrates (p.6 §1). The growth enhancing amount of DHA is about 2,5-60 mg/kg of body weight/day and the amount of ARA about 5-120mg/kg of body weight/day. The amount in the infant formula (per 100 kcal) varies from 2-50mg for DHA and from 4-100mg kcal for ARA (p.7 §2-p.8 §1). That results in about 0,03-1,6% DHA and 0,06-3,3% ARA by weight of the total fatty acids in the formula. The caloric density in claim 7 is within the range of typical infant formulas and can be considered as an implicit feature of D1.

Thus, the subject-matter of claims 1-14 is not new over D1.

2. Document D2 discloses an infant formula comprising 1,5% proteins, 3,6% lipids, 7,2%

carbohydrates. The formula comprises 0,39% ARA and 0,15% DHA by weight of the total fatty acids in the formula. The caloric density is 285 kJ/100 ml (70 kcal/100 ml) (p.2 ln. 11-16 & ln. 35-40; p.5 table 1 & 2).

The subject-matter of claims 1-14 is therefore not new.

3. D3 discloses infant formula (typically containing protein, lipid and carbohydrate) comprising 0,1% ARA and 0,5% DHA (p.103, col.2, §2).

Long-chain polyunsaturated fatty acids (ARA, DHA) are mentioned to play an important role in the growth of infants (see abstract & p. 101 col. 3). The features of claims 7-9 are within a range typical for infant formulas and are considered as implicit features of D3.

The subject-matter of claims 1-11 is therefore cannot be considered as new.